Director, Operational Test and Evaluation

Next Generation Diagnostic System (NGDS) Increment 1

Early Fielding Report

June 2017

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Next Generation Diagnostic System Increment 1
Early Fielding Report

Summary

This report provides the Director, Operational Test and Evaluation's (DOT&E) operational assessment of the Next Generation Diagnostic System (NGDS) in support of a decision to field it to Air Force clinical laboratories in April 2017 prior to Initial Operational Test and Evaluation for shipboard operation and environmental sample analysis capability. The Army, Navy, and Air Force intend for NGDS to replace the currently fielded Joint Biological Agent Identification and Diagnostic System, which identifies biological warfare agents in clinical and environmental samples, to increase the breadth of diagnostic coverage and reduce the manpower, training, and logistics burden on deployable medical units.

This evaluation is supported by data from the operational assessment (OA) of land-based clinical laboratory use of the NGDS conducted by the Army Test and Evaluation Command (ATEC), in coordination with the Air Force Operational Test and Evaluation Command and the Navy's Commander, Operational Test and Evaluation Force, from May 17 – 25, 2016, at Camp Bullis, Texas. Data from developmental testing conducted between July 2015 and December 2016 and the U.S. Food and Drug Administration (FDA) review of the request for classification of the FilmArray NGDS Warrior Panel support this evaluation. Test and evaluation conducted to date is adequate to assess the NGDS operational effectiveness, operational suitability, and survivability for use by land-based deployable medical units in support of medical diagnostic decisions for symptomatic patients.

The NGDS is operationally effective in providing land-based deployable medical units with timely clinical sample analysis to aid in the diagnosis of anthrax, plague, tularemia, Q fever, and the hemorrhagic fevers caused by Ebola and Marburg viruses, in response to a suspected or confirmed bioterrorism event or outbreaks. The NGDS provides increased breadth of diagnostic coverage through compatibility with four FDA-approved commercially available common infectious diseases panels enabling day-to-day use of the system. Clinical laboratory personnel were able to prepare and analyze a clinical sample in an average of 72 minutes versus a requirement of 90 minutes and correctly report diagnostic results for multiple agents at the same time to support medical treatment and force health protection decisions. The NGDS automated sample preparation and analysis process reduces operator sample preparation tasks and minimizes the opportunity for error.

The NGDS is operationally suitable for land-based clinical diagnostic use. The NGDS is easy to use. The infectious disease diagnostic capability enables laboratory personnel to maintain their skillset should a biological warfare agent (BWA) incident occur. The NGDS demonstrated 98 percent mission reliability over 56 analytical runs, exceeding the operational requirement of 94.4 percent probability of completing 5 analytical runs without an operational mission failure. The NGDS demonstrated 96.8 percent operational availability during the operational assessment exceeding the operational requirement of 85 percent.

The classified annex to this report identifies cybersecurity vulnerabilities and potential operational impacts that could occur from their exploitation.

A complete list of recommendations appears at the end of this report. Prior to full fielding of the system, DOT&E recommends the following to improve the NGDS cybersecurity posture:

- The NGDS Program Manager should address the cybersecurity vulnerabilities identified in the classified annex.
- The NGDS Program Manager should conduct cybersecurity testing on the NGDS production representative configuration, which includes a different laptop computer.

System Overview

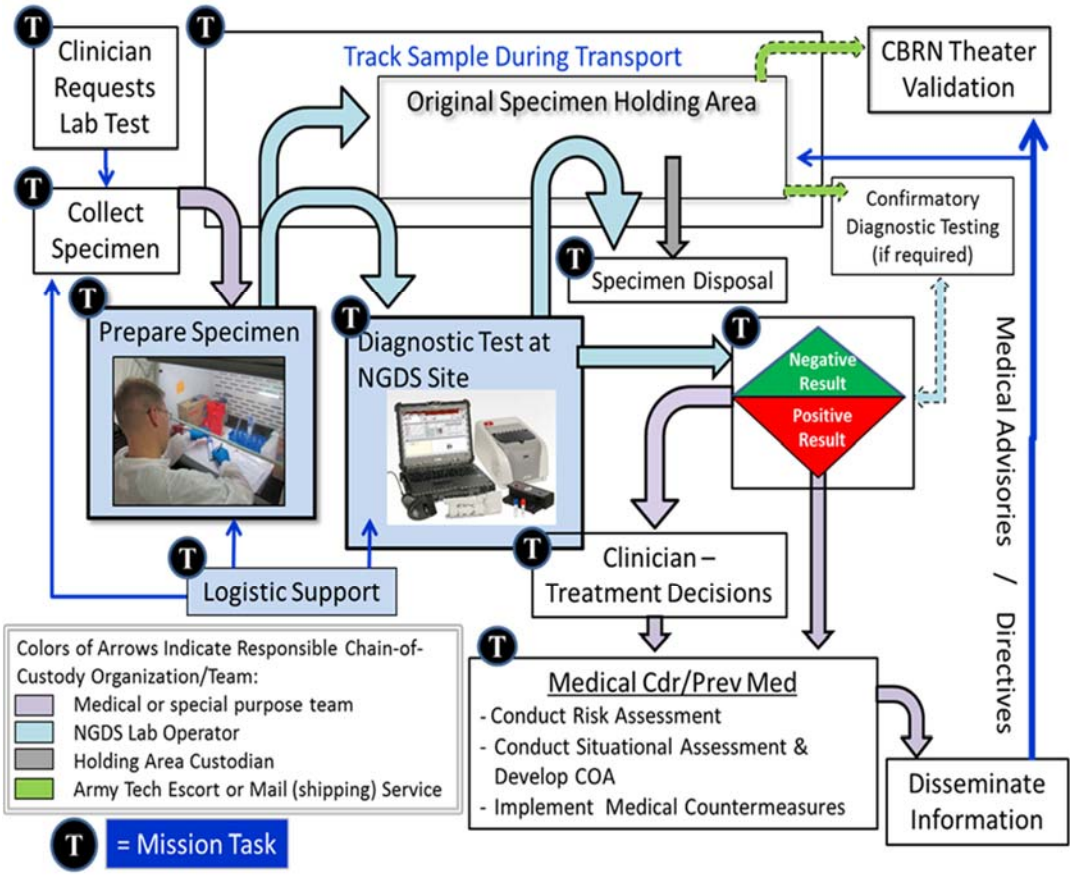
The Services intend for the NGDS to replace the Joint Biological Agent Identification and Diagnostic System (JBAIDS) to identify BWAs in clinical and environmental samples and infectious diseases in clinical samples to support medical treatment decisions, a commander's situational awareness, and force protection decisions. The NGDS is a commercial off-the-shelf polymerase chain reaction analytical instrument manufactured by BioFire Defense, Limited Liability Corporation. Polymerase chain reaction technology is a scientific tool used to detect and identify agent-specific nucleic acids in biological samples.[1] The NGDS program contracted with BioFire to develop two assay panels: the Warrior panel to identify BWAs in clinical samples and the Sentinel panel to identify BWAs in environmental samples, which is still undergoing development and testing.

Mission Description and Concept of Employment

The Army, Navy, and Air Force plan to employ the NGDS Increment 1 in medical support facilities with existing microbiology laboratories equipped with a Class II Biosafety Cabinet, refrigerator, line power sources, lighting, and appropriately trained personnel. Trained clinical laboratory personnel will respond to medical provider requests to analyze clinical samples for the presence of BWA or infectious diseases. The Services intend to employ NGDS in existing environmental laboratories in the future to analyze environmental samples for the presence of BWAs and to inform operational and medical response decisions.

Figure 1 below illustrates the process for clinical use of the NGDS.

[1] Nucleic acids include deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) and comprise the genetic material of bacteria and viruses.



CBRN – Chemical, Biological, Radiological, Nuclear; COA – Course of Action; Cdr – Commander; Prev Med – Preventative Medicine

Figure 1. NGDS Clinical Sample Flow

System Description

The NGDS consists of the BioFire FilmArray 2.0 Polymerase Chain Reaction instrument, a ruggedized laptop computer, software, a ruggedized transport case, a pouch loading system for sample preparation, an optical handheld barcode scanner, an optical mouse, power and communications cables, commercial off-the-shelf and government off-the-shelf consumable assays, reagents, and protocols. Figures 2 and 3 show the NGDS hardware and consumables.

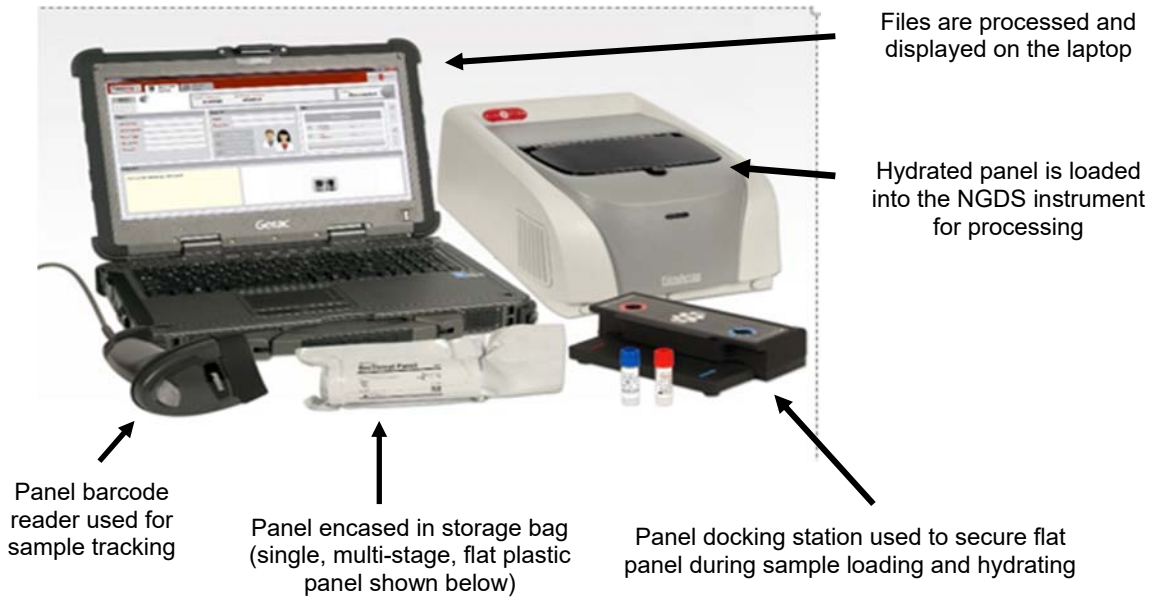
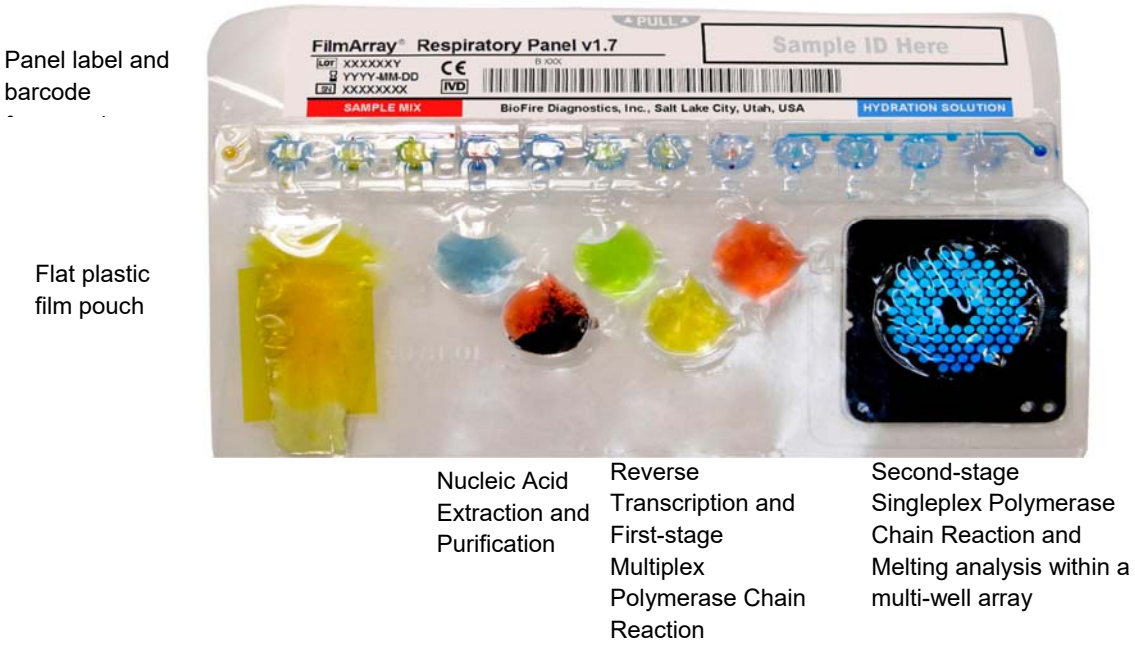


Figure 2. NGDS Analyzer, Barcode Scanner, Laptop, and Sample Preparation Equipment



Note: Colored liquid is for visualization only. FilmArray pouches do not contain colored fluid.

Figure 3. NGDS assay panel showing internal nucleic acid extraction, polymerase chain reaction chambers, and multi-well array chambers used during sample analysis.

Table 1 shows the four FDA-approved commercially available panels for diagnosis of common infectious diseases in clinically relevant matrices available for purchase and use with the NGDS instrument. Tables 2 and 3 list the targets in the Warrior and Sentinel panels.

Table 1. NGDS FDA-approved Commercial Off-the-Shelf Assays

Respiratory Panel	Blood Culture Identification Panel
VIRUSES	**GRAM-POSITIVE BACTERIA**
Adenovirus	Enterococcus
Coronavirus HKU1	Listeria monocytogenes
Coronavirus NL63	Staphylococcus
Coronavirus 229E	Staphylococcus aureus
Coronavirus OC43	Streptococcus
Human Metapneumovirus	Streptococcus agalactiae
Human Rhinovirus/Enterovirus	Streptococcus pneumoniae
Influenza A	Streptococcus pyogenes
Influenza A/H1	
Influenza A/H3	**GRAM-NEGATIVE BACTERIA**
Influenza A/H1-2009	Acinetobacter baumannii
Influenza B	Haemophilus influenzae
Parainfluenza Virus 1	Neisseria meningitidis
Parainfluenza Virus 2	Pseudomonas aeruginosa
Parainfluenza Virus 3	Enterobacteriaceae
Parainfluenza Virus 4	Enterobacter cloacae complex
Respiratory Syncytial Virus	Escherichia coli
	Klebsiella oxytoca
BACTERIA	Klebsiella pneumoniae
Bordetella pertussis	Proteus
Chlamydophila pneumoniae	Serratia marcescens
Mycoplasma pneumoniae	
	ANTIMICROBIAL RESISTANCE GENES
	mecA – methicillin resistance
	vanA/B – vancomycin resistance
	KPC – carbapenem resistance

Table 1. NGDS FDA-approved Commercial Off-the-Shelf Assays (continued)

Gastrointestinal Panel	Meningitis/Encephalitis Panel
BACTERIA	**BACTERIA**
Campylobacter (jejuni, coli and upsaliensis)	Escherichia coli K1
Clostridium difficile (toxin A/B)	Haemophilus influenzae
Plesiomonas shigelloides	Listeria monocytogenes
Salmonella	Neisseria meningitidis
Yersinia enterocolitica	Streptococcus agalactiae
Vibrio (parahaemolyticus, vulnificus and cholerae)	Streptococcus pneumoniae
Vibrio cholera	
	VIRUSES
DIARRHEAGENIC E. COLI/SHIGELLA	Cytomegalovirus (CMV)
Enteroaggregative E. coli (EAEC)	Enterovirus
Enteropathogenic E. coli (EPEC)	Herpes simplex virus 1 (HSV-1)
Enterotoxigenic E. coli (ETEC) lt/st	Herpes simplex virus 2 (HSV-2)
Shiga-like toxin-producing E. coli (STEC) stx1/stx2	Human herpesvirus 6 (HHV-6)
E. coli O157	Human parechovirus
Shigella/Enteroinvasive E. coli (EIEC)	Varicella zoster virus (VZV)
PARASITES	**YEAST**
Cryptosporidium	Cryptococcus neoformans/gattii
Cyclospora cayetanensis	
Entamoeba histolytica	
Giardia lamblia	
VIRUSES	
Adenovirus F40/41	
Astrovirus	
Norovirus GI/GII	
Rotavirus A	
Sapovirus (I, II, IV & V)	

Table 2. Warrior Panel Agents and Clinical Sample Matrices

Disease	Pathogen	Clinical Sample Matrices	
		Positive Blood Culture	Whole Blood
Anthrax	*Bacillus anthracis*	X	X
Plague	*Yersinia pestis*	X	X
Tularemia	*Francisella tularensis*		X
Q Fever	*Coxiella burnetii*		X
Viral Hemorrhagic Fever	Ebola Virus		X
	Marburg Virus		X

Table 3. Sentinel Panel Agents and Environmental Sample Matrices

Biological Warfare Agent	Environmental Sample Matrices
Bacillus anthracis	Culture medium
Yersinia pestis	Aerosol collection buffer solution
Francisella tularensis	Powder/Surface Water collected on swabs
Coxiella burnetii	Soil/Sand
Brucella	Animal Blood
Burkholderia	Vectors (such as insects)
Burkholderia	
Rickettsia	
EEE Virus	
VEE Virus	
WEE Virus	
Smallpox	
Ebola Virus	
Marburg Virus	
Clostridium botulinum	

Test Adequacy

The data from the OA, supplemented by data from developmental testing conducted between July 2015 and December 2016 and the FDA review of the FilmArray NGDS Warrior Panel, was adequate to support this evaluation.

ATEC, with support from the Army Medical Department Center and School and the Air Force Medical Evaluation Support Activity, conducted the OA at the Deployable Medical Systems Equipment Training Site at Camp Bullis, Texas, from May 17 – 25, 2016. Army Medical Department Center and School personnel conducted new equipment training at Fort Sam Houston, Texas, from May 9 – 12, 2016. The OA was conducted in accordance with the DOT&E-approved test plan.

The OA consisted of 15 military personnel from the Army, Navy, and Air Force, staffing 9 laboratories. Each laboratory was equipped with one NGDS system. The laboratories received, prepared, and analyzed 502 threat representative clinical samples spiked with nucleic acids from routine pathogens and BWAs with enough DNA to elicit a response from the system. A laboratory officer oversaw operations at each of the laboratories to ensure accuracy and provide guidance.

Table 4 lists the OA clinical samples provided to each laboratory during the test.

Table 4. NGDS Panel and Sample Specimen Provided to the Laboratories During the OA

Threat	Specimen	Test Panel	Each Lab	Totals per Specimen Matrix	Totals for Microorganism
Respiratory	Nasal Wash +	Respiratory	4	4	17
	Nasal Wash -	Respiratory	13	13	
Bacterial	Blood Culture +	Blood culture	3	3	7
	Blood Culture -	Blood culture	4	4	
Bacillus anthracis	Blood Culture +	WP	2	2	5
	Blood Culture -	WP	0		
	Whole Blood +	WP	2	3	
	Whole Blood -	WP	1		
Coxiella burnetii (Q Fever)	Whole Blood +	WP	3	5	5
	Whole Blood -	WP	2		
Francisella tularensis	Whole Blood +	WP	2	2	7
	Whole Blood -	WP	0		
	Sputum +	WP	4	5	
	Sputum -	WP	1		
Yersinia pestis (bubonic)	Blood Culture +	WP	2	3	6
	Blood Culture -	WP	1		
	Whole Blood +	WP	3	3	
	Whole Blood -	WP	0		
Yersinia pestis (pneumonic)	Whole Blood +	WP	2	2	6
	Whole Blood -	WP	0		
	Sputum +	WP	2	4	
	Sputum -	WP	2		
Marburg Virus	Whole Blood +	WP	2	3	3
	Whole Blood -	WP	1		
At each lab			56	56	56
Across all 9 labs			504		

WP – Warrior Panel

The OA consisted of five threat representative vignettes. Each vignette had notional Forward Operating Bases where personnel contracted an illness associated with a BWA. A Physician's Assistant saw notional patients from each of the Forward Operating Bases. The patients came to the clinic and described symptoms consistent with both BWA and routine pathogens. The Physician's Assistant ordered laboratory testing typically available within Army Combat Support Hospitals based on patient signs and symptoms. Each laboratory received samples for each matrix and agent on the NGDS Warrior Panel; the laboratories received the same sample at the same time. Consistent with realistic operations, the test team provided both positive and negative samples to the laboratories and one set of results was provided to the Physician's Assistant. The patient's symptoms evolved over time, based on documented disease progression. The Physician's Assistant ordered treatment based on laboratory results from the NGDS and notional results provided by the test team. The Physician's Assistant made force health protection recommendations to notional commanders based on the vignette.

The Army Research Laboratory – Survivability Lethality Analysis Directorate conducted a Cooperative Vulnerability and Penetration Assessment from April 19 – 21, 2016, at the Army Medical Department Center and School in Fort Sam Houston, Texas. The Army's Threat Systems Management Office conducted an Adversarial Assessment May 23 – 25, 2016, during the last three days of the OA Record Test. Both assessments were conducted in insider and nearsider postures using the standalone NGDS operational configuration.[2] Once the Services identify NGDS networking requirements for laboratory managements systems and identify plans to integrate the NGDS into a networked configuration, additional cybersecurity testing will be required.

Subsequent to the OA, BioFire Defense decided to upgrade the NGDS laptop in order to utilize the Windows 10 operating system required by the Department of Defense. Additional developmental and cybersecurity testing are required to verify that the upgraded laptop and operating system have not had a negative impact on performance and cybersecurity. Operational and cybersecurity testing with the new NGDS laptop is planned for May – June 2017.

Test Limitations

The OA test scenarios may have affected the evaluation of the time to diagnose a patient suffering from BWA exposure. The OA notional index patients arrived at the medical clinic with advanced signs and symptoms of disease. It is likely that military personnel would seek medical attention before their symptoms reached this stage of severity.

Operational Effectiveness

The NGDS is operationally effective in providing deployable medical units timely clinical sample analysis to aid in the diagnosis of anthrax, plague, tularemia, Q fever, and the

[2] An insider would be someone within the organization that likely has permission to access the system; a nearsider has access to the space but would not have permission to access to the system.

hemorrhagic fevers caused by Ebola and Marburg viruses, in response to a suspected or confirmed bioterrorism event or outbreaks. Proper and timely diagnosis supports medical treatment decision-making and force health protection decisions.

On February 14, 2017, the FDA authorized BioFire Defense to market the FilmArray NGDS Warrior Panel for use with the FilmArray 2.0 system as a medical diagnostic device for use by Department of Defense laboratories, and laboratories designated by the Department of Defense. The FilmArray NGDS Warrior Panel detects and identifies *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, *Coxiella burnetii*, Ebola virus, and Marburg virus nucleic acids directly from human whole blood. Operators will use the FilmArray NGDS Warrior Panel to test for *Bacillus anthracis* or *Yersinia pestis* nucleic acids in blood cultures. A copy of the FDA letter dated February 14, 2017, is attached.

Table 5 summarizes the NGDS with respect to operational performance requirements.

Table 5. Effectiveness

Requirement	Threshold	Demonstrated Performance
Force Protection – Air Force	*Bacillus anthracis* Hemorrhagic Fever Virus [Ebola or Marburg]	*Bacillus anthracis* Ebola virus Marburg virus *Francisella tularensis* *Yersinia pestis* *Coxiella burnetii*
Force Protection – Army, Navy	*Bacillus anthracis* Hemorrhagic Fever Virus [Ebola or Marburg] *Francisella tularensis* *Yersinia pestis* *Coxiella burnetii*	
Regulatory Compliance	FDA-cleared for in vitro diagnostic use	FDA-cleared for in vitro diagnostic use
Sample Preparation Time and Instrument Time to Results	90 minutes	71.6 minutes
Samples per Day	16	20

FDA – Food and Drug Administration

Mission Accomplishment

Army, Navy, and Air Force test units equipped with NGDS demonstrated the capability to use the system to analyze clinical samples and provide accurate and timely information to medical practitioners and command staff to support diagnostic and force health protection decisions. The NGDS capability to analyze environmental samples is still being developed and tested.

The NGDS correctly identified the target in all of the samples during the operational test. During the test, 9 Service medical laboratories used the NGDS to analyze 502 clinical samples,

which included blank samples and samples spiked with synthetic DNA.[3] Table 6 shows the NGDS results obtained during the OA.

Table 6. NGDS OA Sample Analysis Results

Target	Runs Successfully Completed	Number of Samples Reported Correctly	Accuracy* (80% Confidence Interval)
Bacillus anthracis	36	36	(0.94, 1]
Coxiella burnetii	30	30	(0.93, 1]
Francisella tularensis	54	54	(0.96, 1]
Yersinia pestis	71	71	(0.97, 1]
Marburg Virus	18	18	(0.88, 1]
Strep throat	36	36	(0.94, 1]
Flu	36	36	(0.94, 1]
Negative	221	221	(0.99, 1]
Total	502	502	

*Calculated the 80 percent lower confidence interval using the exact Clopper-Pearson method

DOT&E evaluated the timeliness of NGDS diagnostic results to support force health protection decisions based on the operational vignettes and disease progression timelines. During the test, the medical provider ordered initial treatment based on a patient's signs and symptoms while waiting for NGDS or other laboratory results. The medical provider used NGDS diagnostic results to tailor antibiotic treatment to the specific biological agent identified or to cease medication based on NGDS results. Based on NGDS results identifying a biological agent, the medical provider also made force health protection recommendations to command personnel. Table 7 shows the overall diagnosis timelines and results for the five OA vignettes. The time to diagnose a BWA-related disease is dependent upon how quickly sick patients seek medical attention and when a medical provider orders testing for a BWA threat.

[3] While 504 samples were planned, during the OA some tests had to be re-run because of internal assay control failures or NGDS software anomalies. In total, 502 samples were used to evaluate NGDS detection performance and 505 were used to evaluate the reliability requirement.

Table 7. Diagnostic Timelines for Vignettes Portrayed During NGDS OA

Vignette - Agent	Number of Patients with Disease	Correct Diagnosis	Time to diagnose BWA?	Force Protection Measures
FOB 1- Bacillus anthracis	4 – Anthrax 1 – Flu 1 – Staph infection 1 – Parainfluenza	Yes	4 days post-exposure 26 hours after patient arrived at clinic	Isolate Anthrax patients Recommend prophylactics for soldiers in FOB 1
FOB 2 - Coxiella burnetii	3 – Q-fever 1 – Pneumonia 1 – Asthma	Yes	Approximately, 4 days post-exposure 27 hours after first patient arrived at clinic	Isolation of Q-fever patients Notified chain of command Tailored antibiotic regimen
FOB 3- Francisella tularensis	6 – Tularemia 1 – Strep throat 1 – Pneumonia	Yes	Approximately, 6 days post-exposure 30 hours after first patient arrived at clinic	Tailored antibiotics regimen Notified chain of command Recommended prophylactic for soldiers in FOB 3
FOB 4- Yersinia pestis	9 – Plague 1 – Staph infection 1 – Flu	Yes	Approximately, 5 days post-exposure 4 hours after first patient arrived at clinic	Notified chain of command Recommended pest control spray for fleas Recommended prophylactic for soldiers in FOB 4 Anyone with a fever > 100.4 ordered to report to sick call for a NGDS Warrior Panel test
FOB 5- Marburg Virus	2 – Marburg 1 – Staph infection 1 – Flu	Yes	5 days post-exposure 70 minutes after first patient arrived at clinic with obvious hemorrhagic fever symptoms	Isolated Marburg patients Ordered full Personal Protective Equipment for staff Notified chain of command Ordered screening for patients prior to entry into hospital

FOB – Forward Operating Base; BWA – Biological Warfare Agent

The time to receive NGDS test results and diagnose a disease was dependent upon the sample type ordered by the Physician's Assistant. Blood culture samples required the longest time because of the 24-hour culture time required prior to the NGDS analysis. The Centers for Disease Control recommends blood cultures as the gold-standard diagnostic method for some bacterial agents such as *Bacillus anthracis* and *Francisella tularensis*. For blood culture samples, blood is drawn from a patient, inoculated into growth media, and allowed to incubate for at least 24 hours before analysis. For whole blood and sputum samples, the time to diagnose a disease was driven by the time the NGDS requires to prepare and analyze a sample.

For most notional patients, medical treatment began immediately upon entry into sick call based on patient signs and symptoms. Treatment included broad-spectrum antibiotics and breathing treatments. The Physician's Assistant used the NGDS results to refine the selection of prescribed medications, tailoring the antibiotics to the specific agent identified or ceasing medications if they were not warranted based on NGDS results. When the NGDS Warrior panel identified BWAs, the Physician's Assistant used the results to make force health protection

recommendations to the notional commander, including isolation and quarantine of sick individuals, antibiotic prophylaxis, and monitoring for the development of fevers among the affected units.

Operational System Performance

The NGDS provides significant improvements over the currently fielded Joint Biological Agent Identification and Diagnostic System (JBAIDS) that it will replace. The NGDS supports diagnosis of BWA-related illnesses and infectious diseases with similar initial symptoms, which may contribute to more rapid recognition of a BWA-related event. Table 8 compares the NGDS to the JBAIDS.

Table 8. JBAIDS and NGDS Comparison

System Characteristic	JBAIDS	NGDS
Sample Preparation Time	20-40 minutes per sample (Platinum Path extraction kit)	3.8 minutes per sample [3.7, 3.9] 80% CI
Instrument Time to Result	60-80 minutes	67.8 minutes [67.7-68.0] 80% CI
Samples analyzed per run	32 samples per run (including controls)	1 sample
Number of organisms analyzed per run	Max 10 targets - Operator must know what to test for	14-27 simultaneous targets depending on the specific panel
Types of organisms analyzed	Biological Warfare Agents, Influenza	Biological Warfare Agents, many common infectious disease agents identified in Figure 3

CI – Confidence Interval

Operational Suitability

The NGDS is operationally suitable to support medical diagnostic missions. It reduces the manpower burden on a deployable medical unit because it requires less operator hands-on time, is less complex thereby requiring less operator training, and can be used for clinical diagnosis of a range of infectious diseases to maintain operator proficiency.

Table 9 summarizes the NGDS performance with respect to key operational requirements.

Table 9. Suitability

Requirement	Threshold	Performance
Reliability (Probability of completing 5 runs without an operational mission failure)	94.4%	98.4% (80% LCB)
Operational Availability	85%	96. 8% (80% LCB)
Health Data Output Compliance	Health Level 7	Health Level 7

LCB – Lower Confidence Bound

Reliability, Availability, and Maintainability

The NGDS met the user-defined reliability requirement of 94.4 percent probability of completing 5 runs without an operational mission failure with 80 percent confidence during the OA. It did not experience an operational mission failure during 502 analytical runs. The NGDS experienced seven failures during the OA that did not result in an operational mission failure. Table 10 summarizes the NGDS failures that occurred during the OA based upon their effect on the mission.

Table 10. NGDS Failures

Failure Type	Number of Failures	Failure Modes	Mean Runs Between Failure (Point Estimate)	Mission Reliability (80% LCB)
Operational Mission Failure	0	N/A	N/A	98.4%
Mission Affecting Failure	3	2 Control failures 1 analyzer reboot required	168	97.0%
Non-Essential Function Failure	2	2 barcode scanners inoperable	251	98.0%
Rapid Recoverable Event	2	1 analyzer reboot 1 software anomaly	251	98.0%

LCB – Lower Confidence Bound

Mission Affecting Failures occurred during the clinical sample analysis because of assay internal control failures or an analyzer reboot required in the middle of a run. Assay internal controls ensure the chemistry inside each assay pouch has functioned correctly. When a control fails, the system does not alert the operator until the end of the 67-minute run. The sample must be prepared again and analyzed a second time, resulting in a delay of approximately 70 minutes in reporting the results. The Non-Essential Function Failures occurred due to an inoperable barcode scanner. There is no operational impact to an inoperable barcode scanner because the user can simply type the barcode into the NGDS computer software. Operators were able to quickly recover from the Rapidly Recoverable Event failures by rebooting the analyzer or laptop without having to prepare and run another sample.

Developmental testing in December 2016 identified a potential NGDS reliability problem. After exposure to operationally realistic transport vibrations, some of the NGDS analyzer cables were no longer connected. The manufacturer has agreed to make design changes to address the problem. Once planned design changes are complete, the program should conduct a verification of fix test.

The NGDS operational availability requirement is 85 percent. The NGDS demonstrated 96.8 percent availability at the 80 percent confidence level.

The NGDS vendor is responsible for maintaining configuration control as an FDA-approved medical device. As such, there are limited operator-level maintenance tasks that can be performed on the NGDS. These maintenance tasks involve rebooting the analyzer or laptop. If these maintenance tasks do not resolve the problem, operators must return the NGDS hardware to the vendor for repair. In order to maintain capability while systems are with the vendor for repair, the Services plan to maintain spares at depots and other pre-positioned sites to deploy systems as needed.

Training

The NGDS reduces the manpower burden on a unit supporting clinical diagnosis because it requires less operator hands-on time, is less complex thereby requiring less operator training, and can be used for clinical diagnosis of a range of infectious diseases to maintain operator proficiency. In response to an OA survey, NGDS operators indicated that training provided was adequate to support operation of the NGDS. NGDS operators recommended adjustments be made to improve the flow of training materials. They recommended sample preparation procedures be provided in one laminated set of procedures for use during sample preparation. The Physician's Assistant recommended that medical providers at receiving units be provided training on the NGDS capabilities.

Logistics

The NGDS has a smaller footprint than the JBAIDS. The footprint includes the analyzer, system specific support equipment, and consumables. The JBAIDS logistical footprint is approximately 1150 pounds and 87 cubic feet. The NGDS logistical footprint is approximately 62 pounds and 6 cubic feet.

Survivability

The evaluation of cybersecurity vulnerabilities and the potential for operational impacts should these vulnerabilities be exploited can be found in the classified annex to this report.

Subsequent to the OA, BioFire Defense upgraded the NGDS laptop in order to implement the Windows 10 operating system required by the Department of Defense. Additional cybersecurity testing on the production representative configuration is required to reassess the cybersecurity vulnerabilities and potential operational impacts that could occur from their exploitation.

Recommendations

Prior to full fielding of the system, DOT&E recommends the following:

- To realize the potential of the NGDS to expedite recognition that a BWA incident has occurred, the Services should develop and implement plans to educate medical providers at units receiving NGDS on the capabilities provided and the diversity of assays available to support medical diagnostics.
- To improve operational suitability, the Joint Program Manager for Medical Countermeasures should revise organization of training materials for NGDS operators

to improve the logical flow of information and provide sample preparation procedures on a single job aid instead of one for each matrix type.

- The NGDS Program Manager should address the cybersecurity vulnerabilities identified in the classified annex.
- The NGDS Program Manager should conduct cybersecurity testing on the NGDS production representative configuration, which includes a different laptop computer.